



BILLING CODE: 4165-15

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Heritable Disorders in Newborns and Children

Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463, codified at 5 U.S.C. App.), notice is hereby given of the following meeting:

Name: Advisory Committee on Heritable Disorders in Newborns and Children

Dates and Times: May 11, 2015, 8:30 a.m. to 5 p.m.

May 12, 2015, 8:30 a.m. to 4 p.m.

Place: Webinar

Status: The meeting will be open to the public. For more information on registration and webinar details, please visit the Advisory Committee's website:

<http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders>. The registration deadline is Monday, April 27, 2015, 11:59 PM Eastern Time.

Purpose: The Advisory Committee on Heritable Disorders in Newborns and Children (Committee), as authorized by the Public Health Service Act (PHS), Title XI, § 1111

(42 U.S.C. 300b-10), was established to advise the Secretary of the Department of Health and Human Services about the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. In addition, the Committee's recommendations regarding additional conditions/inherited disorders for screening that have been adopted by the Secretary are included in the Recommended Uniform Screening Panel (RUSP) and constitute part of the comprehensive guidelines supported by the Health Resources and Services Administration (HRSA). Pursuant to section 2713 of the Public Health Service Act, codified at 42 U.S.C. 300gg-13, non-grandfathered health plans are required to cover screenings included in the HRSA-supported comprehensive guidelines without charging a co-payment, co-insurance, or deductible for plan years (i.e., policy years) beginning on or after the date that is 1 year from the Secretary's adoption of the condition for screening.

Agenda: The meeting will include: (1) overview of the Committee's authorizing legislation, (2) nomination process for prospective new committee members, (3) discussion of the newborn screening informed consent amendment in the Newborn Screening Saves Lives Reauthorization Act of 2014, (4) update from the Pilot Study Workgroup, (5) presentation on the Assistant Secretary for Planning and Evaluation funded project on the Affordable Care Act's coverage mandate for conditions on the RUSP and the overall costs of screening for state newborn screening programs, (6) presentation by the Newborn Screening Translational Research Network Long-term Follow-up Project, (7) update on the condition review of Adrenoleukodystrophy, and (8) discussion of projects for the Committee's workgroups and subcommittees on Laboratory Standards and Procedures, Follow-up and Treatment, and Education and Training. Tentatively, the Committee is expected to receive comments from states and discuss potential implications of the new legislation, and perhaps to vote on providing such information and/or associated

recommendations to the Secretary for consideration regarding the newborn screening informed consent amendment in the Newborn Screening Saves Lives Reauthorization Act of 2014. This tentative vote does not involve any proposed addition of a condition to the RUSP.

Agenda items are subject to change as necessary or appropriate. The agenda, webinar information, Committee Roster, Charter, presentations, and other meeting materials will be located on the Advisory Committee's website at

<http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders>.

Public Comments: Members of the public may present oral comments and/or submit written comments. Comments are part of the official Committee record. The public comment period is tentatively scheduled for May 11, 2015. Advance registration is required to present oral comments and/or submit written comments. Registration information will be on the Committee website at <http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders>. The registration deadline is Monday, April 27, 2015, 11:59 PM Eastern Time. Written comments must be received by the deadline in order to be included in the May meeting briefing book. Written comments should identify the individual's name, address, email, telephone number, professional or business affiliation, type of expertise (i.e., parent, researcher, clinician, public health, etc.), and the topic/subject matter of comments. To ensure that all individuals who have registered to make oral comments can be accommodated, the allocated time may be limited. Individuals who are associated with groups or have similar interests may be requested to combine their comments and present them through a single representative. No audiovisual presentations are permitted. For additional information or questions on public comments, please contact Lisa Vasquez, Maternal and Child Health Bureau, HRSA; email: lvasquez@hrsa.gov.

Contact Person: Anyone interested in obtaining other relevant information should contact Debi Sarkar, Maternal and Child Health Bureau, HRSA, Room 18W68, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; email: dsarkar@hrsa.gov.

More information on the Advisory Committee is available at
<http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders>.

Jackie Painter

Director, Division of the Executive Secretariat

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